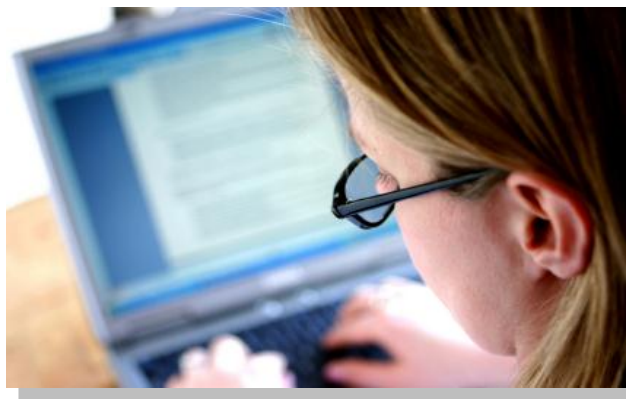


7. VFC COMPLIANCE SITE VISITS

Overview

The CDC requires the Immunization Program to periodically visit VFC providers to assess compliance with program requirements. These visits are called VFC compliance site visits or simply “site visits.”

The goal of the Montana Immunization Program is to ensure provider compliance through effective communication, and a site visit should be considered more of an educational opportunity than an audit. Most program compliance issues are addressed through education. Only cases of repeated and intentional non-compliance progress to escalated follow-up action or termination. Please refer to Section 9 for details on how non-compliance, fraud, and abuse are handled in the Montana VFC Program.



Self-Assessment

We encourage you to continuously assess your VFC compliance, especially prior to a site visit, by using the checklist in Section 8 – VFC Program Requirements. This list details the main requirements of the VFC Program and references sections of this handbook for more information.

Site Visit Process

VFC providers in Montana can expect a site visit from the Montana Immunization Program at least every other year, typically in the spring, summer, or early fall.

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VFC site visits may be combined with other assessment functions of the Montana Immunization Program such as AFIX visits, where facility immunization rates are determined. Only VFC compliance site visit procedures are outlined in this handbook.

Site Visit Preparation

1. Approximately one month prior to your visit, a Montana Immunization Program staff member will contact you by telephone or email to schedule the visit.
2. After the visit is scheduled, you will receive a letter confirming the date and detailing items needed before and during the visit.

During the Site Visit

3. Site visits can take from 1 to 4 hours depending on the size of your clinic, whether other assessment activities are performed, and the compliance issues that arise.
4. Please make the following available during the visit:
 - a. The Vaccine Manager and any key staff involved in the VFC Program
 - b. Three months of temperature logs and Data Logger data from your vaccine storage units

- c. Your completed and annually reviewed *Vaccine Management Plan*
 - d. VFC eligibility screening documentation (if not recorded in imMTrax)
 - e. Borrowing reports (if applicable)
 - f. Your paper stock or electronic source of VISs
 - g. Any VFC-related documentation requested during the visit.
5. Approximately one hour of the site visit will be one-on-one with your vaccine manager. Immunization Program staff asks questions pertaining to the VFC practices at your facility and provide a list of public vaccines shipped to your facility over the last year. They also inspect your vaccine storage units.
 6. After the one-on-one with the vaccine manager, the Immunization Program staff may work independently as they review documents, take notes, fill-out forms, and enter data into the computer.
 7. At the end of the visit, you receive verbal feedback on your compliance and a follow-up plan detailing any corrective actions. There are two types of corrective actions: on-site actions that can be performed during the visit and follow-up actions that require you to correct an issue and submit documentation by a deadline in the future. Repeated or serious non-compliance may result in escalated follow-up. Please see Section 9 Non-compliance, Fraud, and Abuse for details.
 8. Before ending the compliance site visit, a provider representative (preferably the Vaccine Manager or Provider) and the site visit reviewer must sign an acknowledgement of receipt of the follow-up plan attesting that everyone understands any non-compliance issues and the actions necessary to address them.

Requirement

Site Visit Follow-Up

9. In order to remain in good standing with the VFC Program, you must carry out follow-up actions by the deadline. Immunization Program staff will be in contact by telephone, email, or fax or may return to your facility for a follow-up visit.
10. Six months to a year after your visit, you will receive an Interim Site Visit Communication reiterating program requirements and recommendations.

Requirement

Other Visits from the Montana Immunization Program

- **Unannounced Storage and Handling Visits** – The CDC requires the Immunization Program to perform unannounced “spot check” visits throughout the year. Any active VFC Provider could receive an unannounced visit, which takes approximately 30 minutes and focuses on vaccine storage and handling, including an inspection of your VFC vaccine storage units.
- **Educational Visits** – Educational visits are those where the main purpose is education and not assessing compliance. Providers may request an educational visit from the Montana Immunization Program at any time (subject to staff availability). They can also be conducted by telephone or webex.
- **Enrollment Visits** – Enrollment visits occur during the enrollment process, See Section 2 – Provider Enrollment for more information on VFC Program enrollment.

Requirement